A QUARTERLY JOURNAL ON HIV PREVENTION, TREATMENT AND POLITICS

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INSIDE

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What's New?

New Developments in HIV Treatment, Prevention, and Advocacy

HIV and Inflammation: A New Threat

by Donna M. Kaminski, MPH

Traditionally, it was thought that the natural course of HIV included a period of latency – a time when the virus was inactive, often for years. This seemed to be a respite from the harsh effects that HIV can have on the body. But according to recent studies, this "latency period" may not be what it was originally thought to be – in fact, HIV may have a greater impact on the body and immune system than we ever imagined.

Previously, it was assumed that the higher the CD4 count, the greater the level of protection. When CD4 counts were high, the risk for AIDS-defining opportunistic infections and other diseases was thought to be quite low, perhaps even nonexistent. But now we're seeing serious conditions like heart, liver, and kidney disease in people with higher CD4 counts. And we're also seeing more deaths in people whose CD4 counts are above 200. It appears that during this period of "latency" HIV is not silent, that CD4 levels may not indicate what is happening inside the body, and that inflammation may be affecting many organ systems. So the question is, how is this happening?

To answer this, we can look at the SMART study, one of the first to reveal this effect. In this study, people who stopped their HIV meds when their CD4 count rose above 350 had higher rates of AIDS-defining opportunistic infections and non-AIDS conditions, as compared with those who stayed on HIV therapy. They had higher amounts of virus in their blood, and those higher levels were associated with inflammation.

What Is Inflammation?

When the body fights invaders like viruses or bacteria, or repairs injured tissues, fluid and cells get transported to the site of injury. As the body heals, the cells can

continued on page 3

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ACRIA Trials in Progress

Pomegranate Juice
People who have not taken HIV meds for at least 90 days will drink pomegranate juice or placebo juice daily for 10 to 18 weeks to study its effect on the heart, quality of life, and HIV viral load.

Crofelemer for Diarrhea
People 18 and older who have persistent diarrhea will take crofelemer (a new anti-diarrhea drug) or placebo tablets for 6 weeks. Then everyone will take crofelemer for 5 months.

Ibalizumab
People who have taken HIV drugs will receive infusions of ibalizumab (a monoclonal antibody designed to block HIV entry into CD4 cells) twice a month for 24 weeks or longer, along with other HIV drugs.

For more information on these trials, contact us at 212-924-3934, ext. 121.

Medicaid Managed Care for People with HIV in NYC

In August, 2010, the Department of Health will begin to expand mandatory managed care enrollment in NYC to Medicaid beneficiaries with HIV. People with HIV who are currently exempt based on their HIV infection will no longer be considered exempt from mandatory enrollment in Medicaid managed care. HIV-positive people with Medicare, ADAP, other Medicaid exemptions or exclusions, or private insurance will not be affected by this change.

For more info, visit the New York State DOH website:
www.nyhealth.gov/health_care/managed_care

which includes a link to "Medicaid Managed Care for People with HIV and AIDS."

And the New York City DOHMH website:
www.nyc.gov/health/managedcare

which Includes information for consumers and a link to "What Managed Care Plans Are Available in My Neighborhood?"

Social Security for People with HIV

If you have HIV/AIDS and cannot work, you can now apply online. for disability benefits from the U.S. Social Security Administration.

For information on eligibility visit:
www.socialsecurity.gov/pubs/10019.html

To apply online for Disability Benefits:
www.socialsecurity.gov/applyfordisability

Visit the Social Security Administration's website at **www.socialsecurity.gov** for an online suite of services.

HIV and Inflammation *continued from first page*

swell, get warm, and become sore. One theory is that as HIV chronically infects the body, cells and tissues are destroyed and then heal, activating the immune system. That leads to an overstimulated immune system that can become burned out or weakened. So, even though a lab result may show a high CD4 count, the amount of inflammation in the body may be causing damage on a cellular level.

And that can lead to heart, liver, kidney disease, and greater levels of bone loss.

Evidence shows that while HIV medications may play a role, they are not the only culprit. During the SMART trial, when people who stopped their HIV meds restarted them, levels of inflammation decreased but never became normal. There remained a residual level of inflammation (shown by increased levels of IL-6 and D-dimer) and a greater number of cardiovascular events occurred, especially in people who started the study with undetectable viral loads. Why was this of concern? Because high levels of inflammation are thought to increase atherosclerosis (narrowing of the arteries) and heart disease even in people who don't have HIV. In the SMART trial, there were higher rates of heart, liver, and kidney disease among people with HIV at younger ages, even after controlling for differences in age and gender.

Research presented at the most recent Conference on Retroviruses and Opportunistic Infections in San Francisco provided further support of inflammation as a source of cardiovascular disease. In a study presented by Priscilla Hsue, the thickness of the carotid artery in the neck was measured by ultrasound among 285 people with HIV and compared with those of HIV-negative people. Among those with HIV, the carotid artery was significantly thicker, and lined with greater levels of plaque, placing them at greater risk for cardiovascular problems. In addition, they found the thicker arteries to be associated with high levels of a known inflammatory marker linked to heart disease called C-reactive protein. Another study found similar effects but found the artery thickness to be lower in people on HIV meds or with CD4 counts above 400. But it was never as low as in those who are HIV negative.

The first study also looked at how well the brachial artery could dilate, or widen, and whether it was becoming stiff due to inflammation. When they compared 98 people who were taking HIV meds with people who were HIV-negative, they found that even when HIV was well controlled with meds, the arteries were stiffer and not able to dilate in response to stress.

Increases in blood levels of several markers of inflammation have been linked with HIV disease. In addition to C-reactive protein, other markers such as interleukin-6, D-dimer, and TNF-alpha were also found to be elevated in people with HIV with thickened arteries. Higher levels of MCP-1 and RANTES are also seen in people with HIV, and can mean higher levels of protein in the urine, and kidney disease. The higher levels of inflammatory proteins seen in people with HIV (whether or not they are taking HIV meds) may suggest that HIV may be responsible for the heart, liver, and kidney disease that is seen at higher CD4 counts.

Inflammatory Markers and Mortality

The big question is whether increased inflammation affects the lifespan of people with HIV. Early studies suggest it could be linked to all causes of death among people with HIV. A study by Kalayjian explored the link between inflammatory markers and AIDS deaths. In the study, people who had never taken HIV medications started medications during the trial. Those who later developed AIDS or died during the study had their inflammatory markers measured (specifically TNF, IL-6, CD27, and CD40). The researchers found that there were higher levels of all these markers in people who developed a new AIDS-defining illness or who died before they started HIV meds. Levels of TNF, CD27, and CD40 were higher before HIV treatment was started in people who later developed an AIDS-defining cancer or who died. This occurred about a year after they started HIV meds, even though most of them had undetectable viral loads and CD4 counts above 200. So it would appear that inflammation may be causing damage early in the course of HIV disease, despite lower viral loads and higher CD4 counts, and that it may play a role in both HIV-related cancers and death.

Aging Before Your Time?

HIV may also lead to premature aging. In one study, vasodilation, or the blood flow, of people with HIV seemed to look like that of HIV-negative people who were 10 to 15 years older. Another study found the blood vessels of people with HIV appear to be similar to those of HIV-negative people who are 25 years older.

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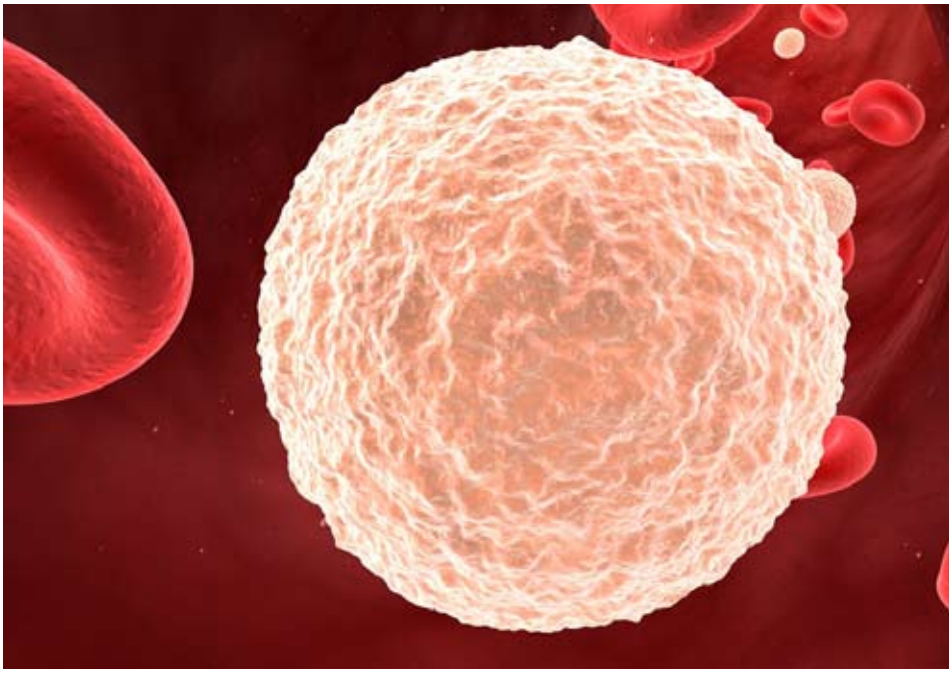
The T cells of people with HIV look like those of people without HIV who are 32 years older – while the median age of HIV patients in one study was 56, their T cells looked like those of patients who were 88. (The people with HIV had fewer CD8 cells, specifically those with CD28 and CD56 markers.) Further, people living with HIV for 8 to 12 years were 15 times more likely to be frail as compared with their HIV-negative peers. And the thymus gland, which helps T cells to mature, appears smaller in people with HIV.

All of these findings indicate that HIV seems to be linked with diseases normally seen at older ages, and that chronic HIV infection may create a state of premature aging and inflammation. If this is the case, what can be done to protect people with HIV from these serious non-AIDS conditions?

The short answer is that we're not sure. One idea was to try Valcyte, a drug that reduces levels of cytomegalovirus (CMV), which was thought to lead to inflammation in people who had both CMV and HIV. But in one small trial, it didn't reduce the levels of residual inflammation. ACTG 5256 studied Selzentry, a new HIV receptor blocker, to see if adding it to people's standard HIV meds could lower inflammation. Inflammatory markers did go down, but the study couldn't tell whether this led to fewer cardiovascular events or higher CD4 counts. The "Jupiter" study (done in HIV-negative individuals) found that when people who had low LDL cholesterol but high C-reactive protein took the anti-cholesterol drug Crestor, they had 44% fewer cardiovascular events. But some studies have shown the opposite. We need further studies combining Selzentry with statins like Crestor to see if that could lower the markers of chronic inflammation and actually improve the health of people with HIV.

Several groups are looking at whether intensifying treatment by using more than the current standard of three HIV medications may reduce chronic inflammation. Some researchers have started to look at whether immune suppressants like prednisone, hydroxyurea, cyclosporine, and mycolic acid could help. Others are looking at medications like Renagel or colustrum supplements to keep microorganisms from leaving the gut and spreading inflammation throughout the body. Still others are looking at using chloroquine, a medication used for malaria. Common over-the-counter medications like Motrin and Aleve are also being tested for their ability to reduce chronic HIV inflammation.



The T cells of people with HIV look like those of people without HIV who are 32 years older – while the median age of HIV patients in one study was 56, their T cells looked like those of patients who were 88.

In addition, some researchers are studying whether the thymus can be stimulated to produce more T cells. Clinical trials are planned of Serostim, a human growth hormone, and Sirolimus, an anti-rejection drug used in transplant patients, to see if they can reduce inflammation by bringing more CD4 cells onto the scene. Researchers at the French-based biotech Cytheris have studied IL-7 to see if it can increase CD4 counts in order to lower inflammation. IL-6 has also been further explored in clinical studies. And yet another group is looking at an immune-based therapy called Esbriet.

Some studies in rats and dogs have found that reducing the number of calories eaten may slow the aging process. A drug called resveratrol, which may have the same effect as calorie restriction, is being studied. Also, as we age a part of our chromosomes known as telomeres have been found to shorten, so researchers are looking into whether telomerase activators might slow the aging process in people with HIV. Finally, other groups are looking at vitamin D and omega-3 fatty acids as a way to slow the premature aging process seen in HIV.

Conclusion

It will take more studies before we know how to prevent heart, liver, and kidney disease in people with HIV. But one thing seems clear: HIV isn't sitting silently during its "latency period." Indeed, it is quite active, leaving a significant imprint on the body's immune and inflammatory systems. ■

Donna M. Kaminski is a fourth-year medical student at UMDNJ-SOM, and ACRIA's former Associate Director of Treatment Education.

HIV Prevention: A Changing Outlook

by Deirdre Grant and Sarah Littlefield

In 2009, research into new HIV prevention methods had its ups and downs: A once-promising microbicide failed, attention turned to HIV drugs as the "next best thing" for HIV prevention, and for the first time, encouraging data for an AIDS vaccine emerged. New data from a range of prevention trials are expected in 2010. While none of the approaches being tested will replace current methods of prevention – condoms, behavior change counseling, needle exchange, harm reduction, etc. – each presents the possibility of adding a new prevention option, changing the HIV prevention world. And that could help protect millions of people around the world.

AIDS Vaccines

The Thai Trial: A Shot in the Arm

Though dozens of AIDS vaccines have been tested over the years, until recently, not one had been shown to reduce the risk of HIV infection. But in September 2009, important results from an AIDS vaccine trial were released. The RV144 study, also known as the "Thai trial", took place in Thailand from 2003 to 2009. It was the largest AIDS vaccine trial to date, with over 16,000 participants. The trial studied two vaccines, ALVAC and AIDSVAX, and found that the regimen may have provided a modest protective effect. This was surprising, in part because AIDSVAX alone had already been tested in two large trials where it was found not to be effective.

There were 51 infections in people who received the vaccines and 74 in people who received a placebo (a dummy shot). Put another way, there were about 30% fewer infections in people who received the vaccines compared with those who received the placebo. This suggests that the vaccine provided some level of protection. But if any vaccine that was 30% effective was made available, people would need to know that it did not eliminate the risk of HIV infection, and that it would need to be used with a proven prevention method like condoms. There is also a slim possibility that the result was due to chance. And, it looks like most of the protective effect of the vaccine occurred during the first year of the study – possibly a temporary benefit that waned over time. The study is now being followed up with other research to try to understand whether any immune responses induced by the vaccines can protect against HIV.

Other Vaccines

The encouraging results from the Thai trial came two years nearly to the day after we learned that Merck's MRK-Ad5 vaccine – the best hope for a vaccine at the time – was not effective. There were two large-scale trials of the Merck product: the Step trial, which took place in the Americas and Australia, and the Phambili trial in South Africa. The Step trial was stopped early, in September 2007, after a review of the data revealed the vaccine did not protect against HIV.

Further analysis appeared to show that some people who received the vaccine were more rather than less likely to become infected if they were later exposed to HIV. Longer-term follow-up showed that uncircumcised men who got the vaccine had a higher risk of acquiring HIV.

Researchers had hoped the Merck vaccine would lower viral loads in people who received the vaccine but later became infected. This is one goal of AIDS vaccines, though it is different from how the public generally understands vaccines. One approach scientists are trying is an HIV vaccine that targets the cellular arm of the immune system; since cellular defenses act after cells have been infected, they are not expected to be able to protect completely against infection. An HIV vaccine targeting cellular immunity could lead to lower viral loads in people who got the vaccine but later got HIV.

A vaccine that doesn't prevent infection, but keeps you from getting sick? We generally assume that vaccines provide complete protection against infection. In fact, not all approved vaccines provide 100% protection to all people who receive them. But they do provide high levels of defense – enough effectively to prevent disease. Approved vaccines teach the body to make antibodies against the viruses or bacteria in question. Antibodies target foreign invaders in the body before they are able to infect cells. Today there are efforts to develop AIDS vaccines that target both cellular and antibody defenses. Scientists think that this one-two punch of immune defenses is the best hope for a vaccine.

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Currently, the largest ongoing AIDS vaccine trial is the HVTN 505 study, which plans to enroll over 1,300 men who have sex with men in the U.S. The trial is studying a cellular vaccine strategy, looking at the vaccine's safety and its effect on viral load in people who become HIV positive during the study (the vaccine itself cannot cause HIV infection). A complete list of vaccine trials can be found at www.avac.org/trials.

Why has AIDS vaccine research been so challenging?

HIV infects the cells of the immune system and has highly effective strategies to evade the body's defenses. Developing a vaccine that can outsmart these strategies is a difficult task, especially since HIV mutates so often. Even when effective defenses emerge, the virus can often escape from immune control.

The results from the Thai trial were the first to suggest that a vaccine may lower the risk of infection. In the coming years, researchers will work to build on that possibility, but it will likely take many years to develop a highly effective vaccine.

What's next?

Researchers are working to determine why Thai trial participants who received the vaccine had slightly lower rates of infection than those who received the placebo. The Global HIV Vaccine Enterprise – a group of organizations working to speed the development of a preventive vaccine – is also updating its Scientific Strategic Plan for the AIDS vaccine field, to be released later in 2010. In addition to efforts around understanding the results of the Thai trial, there is ongoing work on antibody vaccines and improved T-cell vaccine candidates.

PrEP

Can a pill a day prevent HIV?

Pre-exposure prophylaxis, or PrEP, is an experimental prevention strategy using approved HIV drugs. Several trials are studying whether the use of HIV meds by HIV-negative people can reduce their risk of HIV infection. Animal studies have shown a high level of protection against infection when HIV drugs were given before exposure to SHIV (an HIV-like virus that can cause disease in monkeys). For years, HIV drugs have been given to HIV-negative infants born to mothers with HIV. Post-exposure prophylaxis also uses HIV meds in people who think they've had a recent HIV exposure. These examples support the study of PrEP in clinical trials.

Current PrEP trials involve nearly 20,000 HIV-negative people from different populations in over a dozen countries. They are studying Viread or Truvada taken once a day, and some small studies are also looking at PrEP regimens that aren't taken daily.

By this fall we should hear results from a large safety trial sponsored by the CDC, which enrolled men who have sex with men from Atlanta, Boston, and San Francisco. The trial was designed as an expanded safety study, so we will not get effectiveness results from this trial. Initial results from several large effectiveness trials are anticipated in late 2010 and early 2011.

There is, of course, hope that these trials will report positive results and make PrEP a viable new prevention option. But even if PrEP is shown to reduce the risk of HIV infection, there will still be challenges to making it available.

First, there are questions that the current trials won't be able to answer. For example, we will still need to find out if there are long-term safety issues, if PrEP is safe for pregnant women and adolescents, and if resistance is an issue.

In the U.S. (and elsewhere), one of the most common questions about PrEP is, "Who will pay for it?" In an era of ADAP waiting lists and a new health reform law, the answer is not yet clear. While generic Truvada costs as little as $143 a year in developing countries, its retail price in the U.S. is $14,000 a year. It's not known whether private insurance will cover that cost – and imagine the debates on whether Medicaid should pay to protect so-called "risky" gay men.

Also, if PrEP does work, it will likely be only partially effective. It's not expected to provide 100% protection or to be a replacement for other prevention options like condoms or clean needles. In the real world, the effectiveness of PrEP will depend on the degree to which people take PrEP drugs as prescribed. Effectiveness would also be hampered if people increased their risk behaviors. In addition, there are concerns about giving healthy people HIV meds for long periods of time. PrEP, like any other new strategy, would need to be introduced in programs that had thorough, ongoing counseling for its users.

Microbicides

A microbicide is a substance designed to prevent or reduce the sexual transmission of HIV and other sexually transmitted infections when applied inside the vagina or rectum. Microbicides may be gels, lubricants, or creams and could be applied through applicators, suppositories, or vaginal rings.

So far, results from large clinical trials of microbicides have been disappointing: Three vaginal gels – Carraguard, BufferGel, and Pro2000 – were found to be safe but not effective, and three trials suggested the product being tested may be harmful (Nonoxynol-9, Savvy, and Cellulose Sulfate).

Despite these disappointments, researchers are conducting new trials of microbicides that contain HIV drugs. These products consist of gel formulations of HIV drugs that can be applied to the vagina or rectum. It is hoped that these microbicides will be more potent against HIV and last longer in the vagina and rectum than those previously tested, and that they will not result in the creation of resistant virus.

Hope in 2010

The CAPRISA 004 trial, conducted in South Africa between 2007 and 2009, is the first large trial of a vaginal microbicide containing an HIV drug to be completed. The trial studied the safety and effectiveness of a gel containing tenofovir (the drug in Viread), and results are expected in July 2010.

The results of this study will be important to the future of the microbicide field. If it shows that this gel has an impact on women's risk of HIV infection, it will be the first microbicide trial to have a positive result. Follow-up research would of course be needed to confirm and explore the result before it could be approved for widespread use.

If the CAPRISA 004 trial does not show the gel to be completely effective, there are two possible outcomes: that the gel was clearly not effective or that it was partially effective. But if it does not prove effective, advocates and researchers will need to unite in support of future trials. Critics may question the continued funding of large trials if product after product fails to prove effective. But more trials are important to move the field forward. Each trial has a unique design and population, and each moves the field closer to the goal of providing women and men with an additional prevention method that they desperately need.

Other trials of microbicides containing HIV drugs are ongoing or in the planning stages. One such trial, the VOICE study being conducted by the Microbicides Trial Network (MTN) in countries in Southern Africa, is comparing the safety and effectiveness of the same gel studied in CAPRISA 004, and two different PrEP regimens (Viread or Truvada pills). Results are expected in 2013. Many of the research organizations in the microbicide field have also planned vaginal ring studies as a way to deliver a microbicide. Some of the studies test the acceptability of a vaginal ring, as this technology has never been used for this purpose before.

Rectal Microbicides

Compared with vaginal microbicides, rectal microbicide research is in its infancy. Political and cultural reluctance, a lack of funding, and scientific challenges have all contributed to the delay in their development.

The vagina and rectum are two separate and biologically different compartments in the body. It is very important that any vaginal microbicide in late-stage clinical testing also be tested for rectal safety, since a vaginal microbicide that is readily available will most likely also be used rectally, regardless of whether that use is approved.

To keep the field of rectal microbicides moving forward, the group International Rectal Microbicide Advocates (IRMA) estimates that $10 million will be needed annually from 2011 to 2014 (a 40% increase from the 2010 estimate), and $44 million annually from 2015 to 2020 (over six times the investment expected this year). Between 2007 and 2010, the U.S. government contributed over 91% of rectal microbicide funding. Efforts must be made to find more diverse funding sources.

This year holds great hope for microbicides as we await the result of the CAPRISA 004 study. If this gel is found to be effective, a renewed vigor will keep the field moving forward Regardless of the CAPRISA outcome, other trials continue and are planned in the search for an effective microbicide.

Conclusion

By the end of 2010, the landscape of HIV prevention will be different regardless of the trial outcomes. Researchers are hopeful that results from clinical trials of HIV vaccines, PrEP, and rectal and vaginal microbicides will provide promising results for the future of HIV prevention. None of these interventions will be the answer to ending the HIV epidemic. But some or all of these options may be an important part of a comprehensive response that will curb the spread of the disease. ■

There are many research advocacy groups that track ongoing HIV prevention research. For more in-depth and up-to-date coverage, including details on ongoing research, please visit:

- ***AVAC: Global Advocacy for HIV Prevention***
  www.avac.org
- ***CDC PrEP page***
  cdc.gov/hiv/prep
- ***Global Campaign for Microbicides***
  www.global-campaign.org
- ***International Rectal Microbicide Advocates***
  www.rectalmicrobicides.org
- ***PrEP Watch***
  www.prepwatch.org

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Take a number, please.

by Amy Bell-May

I remember it like it was yesterday. Back in 2004, I took an HIV 101 class at the correctional facility I was in, and they offered free HIV testing. When my result came back positive a week later, I was confused and just wanted to die. Not only was I HIV positive, I was also battling depression, drug abuse, domestic violence, incarceration, family issues, and a lot of bad choices I had to face up to. When I was released from that awful place I wanted to try and change, but change is not so easy when facing so many things at once. So I continued on that path of destruction for another three or four years.

Since the day I found I had HIV, I have always been very open about my status, but very fearful of HIV medications. I had heard so many horror stories from my HIV-positive friends about the side effects that the meds can cause. So I was happy that I didn't need to go on them, based on my CD4 count. Then, in March of 2010, my CD4 count dropped and my viral load spiked. My doctor, Mark Call, told me it was time for me to think about going on medications. He was a great doctor to talk with and very helpful. Since I was fearful and had a lot of concerns about side effects, we decided on Truvada and Isentress. It turns out that my fear was silly, because those meds have made me feel better, not worse. I am not so tired and exhausted all the time, and I am a better person to be around.

My doctor knew that the South Carolina AIDS Drug Assistance Program (ADAP) once again had a waiting list because of funding cutbacks. So they worked it out for me to get a three-month supply of medications from Gilead.

My doctor knew that the South Carolina AIDS Drug Assistance Program (ADAP) once again had a waiting list because of funding cutbacks. So they worked it out for me to get a three-month supply of medications from Gilead, through its Patient Assistance Program. I was approved based on the fact I did not make enough money at work, and I didn't have any insurance.

I then went to my case manager at AIDS Upstate, Marcey Chatman, and she explained how to apply for ADAP. Marcey and AIDS Upstate are really great – they have helped me a lot along the way. They have gotten me counseling, housing assistance, job hunting assistance, even a food pantry. Anything you can think of that you may need help with, they have it to offer – but they've been affected by the South Carolina budget cuts as well.

About a month after I started my medications I received a letter in the mail that stated:

> *Dear Ms. Bell-May,*
>
> *This is to acknowledge receipt of your recent application to the South Carolina Drug Assistance Program. Due to limited funding for this program we currently have no openings available. Your name will be placed on our waiting list, and as soon as possible we will get you enrolled in the program. You will be notified in writing when an opening occurs.*

I was expecting the letter but I guess I was hoping that I would somehow get something more than just a short letter. It seemed so final, like someone just handed you your death certificate. The fear that I had overcome returned all over again. Now I sit and wonder what happens next. I have called my case manager, mentors, and everyone else, but they only know as much as I know. Without the help of the legislators what else can we do? It's not like we can change the outrageous price of the drugs, and it's not like we can get them for free. So I am left to sit and wonder: will I get my medication or will I have to be like the people who have already died on our waiting list? I am 29 years old and I want to be able to live a healthy life and be treated equal to everyone else.

I don't know what will happen when my three-month supply of medication runs out. I'm worried because if you miss doses you build up resistance and the medications will not work anymore. There are only so many regimens to choose from, and so many

I have stood up for what I believe in. I have spread the message of the HIV prevention measures that our next generation can take. I have empowered myself and other people with HIV to advocate for themselves. I want to live life, be treated equally, and be remembered for what I do even when I'm gone.

times you can change before you run out of options or they just don't work anymore. And the side effects I worried about may be more likely on other regimens. Also, I'm on a two-pill-a-day regimen. How would you like to have to take four or five pills a day? That's another thing that could happen if I become resistant.

All this just makes me want to fight even harder. I don't give up as easy as I once did. The legislators do not realize that when they cut the budget they are letting people like me die. You see, I have come along way. I am the mother of a daughter, I am a daughter, a granddaughter, and a sister. I am an employee, a taxpayer, a registered voter. I am clean and sober, and I am an advocate. I have done many speaking engagements. I have stood up for what I believe in. I have spread the message of the HIV prevention measures that our next generation can take. I have empowered myself and other people with HIV to advocate for themselves. I have became part of a women's health advocacy network called P.O.S.I.T.I.V.E. VOICES (Proactive, Optimistic, Sisters, In Touch, Involved, Validated and Empowered), and I am also a peer educator. I want to live life, be treated equally, and be remembered for what I do even when I'm gone.

Don't the legislators know that it costs less to treat this disease now instead of later, or do they just not care? Providing medications to patients is cheaper than the hospital stays it will create for them later if they do not get their medications. It is also an increased risk to our communities if HIV is not treated now, because it could lead to more HIV cases later. It will lead to more PWAs on disability because they can't work, and more people on Social Security, which already is a problem. This will ultimately lead to what they are trying to prevent: more cost to taxpayers.

All of South Carolina came together and formed a task force of AIDS service organizations, consumers, and PWAs, and even after all our collective efforts, the legislators still cut our budgets by millions, and created the ADAP waiting list. Our list is approaching 100, and already one person has died. If we don't get the money we need 900 people who are already getting their meds from ADAP will have to be taken off, creating even more problems for our state. We are going to have to stand up and be strong or the South is going to fall, with injustice for us all! ■

The Testing Debate

Is Written Consent A Barrier?

by Tracie Gardner and Daryl J. Cochrane, MPA

There is a growing urgency among policy makers and public health authorities to reduce the high rates of new HIV infections in the U.S. Thousands of people who are HIV-positive are unaware of their status. As a result, they do not seek the medical care that can prolong their lives and prevent transmission to others.

The CDC estimates that over a million people in the U.S. have HIV but that over 230,000 of them don't know it, with about 56,000 new cases each year. Due to the alarming number of people becoming infected, the CDC urged states to make HIV testing a routine part of medical care. They also recommended two changes in HIV testing: "opt-out" testing (an HIV test would be given unless a patient chose not to have one) and the elimination of written HIV consent (a general medical consent form could authorize HIV testing). The rationale for this was based on several developments, including the evidence that HIV treatment is more effective when started earlier, that HIV testing is less expensive than ever before, and that people who know they have HIV are less likely to transmit it.

Opt-out testing is quite different from opt-in testing, in which a provider asks patients if they would like to get tested for HIV. Those who support opt-in testing claim that a test is not useful unless a person knows what the test means and is then able to take steps either to get medical care or to avoid getting HIV in the future. They feel that opt-in testing requires a separate "informed consent" process that is lost with opt-out testing. Advocates for opt-in testing argue that informed consent is essential, since people are unable to provide consent without first being informed. In other words, "uninformed consent" is not consent at all. This is the central point of the argument, one that advocates on opposite sides of the issue do not agree upon.

Those looking to follow the CDC's guidelines claim more people will be tested for HIV, particularly in communities that have been hit the hardest by HIV, such as communities of color. They believe it will also help decrease HIV stigma. Several national organizations support the CDC's recommendations, including the American Medical Association, the American College of Physicians, and the HIV Medicine Association.

> The CDC recommended two changes in HIV testing: "opt-out" testing and the elimination of written HIV consent.

The Debate in New York

New York City is the epicenter of the U.S. AIDS epidemic, with one out of every nine AIDS cases. New York City has more AIDS cases than Los Angeles, San Francisco, and Washington, D.C., combined. Over 80% of new AIDS diagnoses and deaths in New York City are among black men and Latinos. Nearly a third of new HIV diagnoses are among women, especially black and Latina women, and half of those women were infected by a man who did not know he had HIV.

New York State is currently one of eight states that require separate written consent for HIV testing, but that policy is being debated. On December 1, 2005, Dr. Thomas Frieden, then the New York City Health Commissioner, wrote an editorial in the *New England Journal of Medicine* stating that the stigma and discrimination surrounding AIDS had decreased to the point where public health policies specifically for AIDS were no longer necessary. As a result, he proposed changing New York State's HIV policies to match the recommendations provided by the CDC, changing to opt-out testing.

There is also a strong and vocal element among New York medical professionals, service providers, and advocacy organizations for communities of color that maintains that HIV testing laws should be changed due to the number of people who don't know their status, those who come into care with late-stage diagnoses, and the high number of AIDS cases in communities of color. This group includes Patrick McGovern, executive director of Harlem United Community AIDS Center, a proponent of changing New York State law to eliminate pre-test counseling, adopt opt-out testing, and allow for oral consent documented in patients' charts. He reflects the perspective of those who believe that these changes are necessary to reduce stigma, address people's reluctance to test, and remove written consent as a barrier.

McGovern points to Washington D.C., which encourages opt-out testing in medical settings and has seen the number of HIV tests increase from 43,271 to 72,864 in one year, with people diagnosed at higher CD4 counts. He also points to a 2009 study of the San Francisco Department of Health's testing program that showed a correlation between written consent laws and a 12% reduction in HIV testing, compared to 33% increase in monthly HIV testing rates after written consent was dropped. McGovern questions the value of written consent when compared to timely access to lifesaving therapies.

However, there has been significant push-back from HIV activists who think this approach ignores the strong stigma and discrimination surrounding AIDS. These activists believe that eliminating a separate written consent form for HIV testing is not the way to raise testing rates, and that it fails to address the real barriers to getting an HIV test.

Advocates point to data showing that health care providers are failing to offer HIV tests to their patients. Many health care providers don't ask patients to be tested for HIV because they are not

trained in HIV counseling, are uncomfortable discussing HIV, or feel the patient is not at risk for infection. Increasing the number of health care providers who offer HIV testing is critically important in making people aware of their HIV status. There is enormous potential to test more people for HIV by shifting the request for testing from patients and HIV service providers to the general medical community.

In fact, studies show high testing rates when patients are asked by their doctors. For example, under the current law, 95% of pregnant women who are offered testing consent to it. This, coupled with the use of HIV drugs during pregnancy, has brought down HIV transmission rates from mother to infant from around 25% to less than 2%.

There is also evidence that HIV testing rates in New York City are already rising under the current law. There has been an increase in the number of people tested resulting from a recent initiative to offer rapid HIV testing routinely to patients seen in health care facilities.

Barriers To Testing

The main impetus behind any change in HIV testing is simply to get more people tested. An uptick in the number of people tested gets those who test positive into care and makes them aware of their HIV status, helping to prevent further transmission. We know that nearly 70% of new infections are caused by people who are unaware they are positive. Decreasing that number will significantly affect the rate of new infections. Further, early detection of HIV will result in fewer people being diagnosed with AIDS at the same time they receive their HIV diagnosis.

The barriers to HIV testing generally fall into one of the following categories – informational, psychological, or physical. These are not only barriers for the patient, but for also the providers.

Dealing with informational barriers is often the first step in dispelling myths about HIV and setting a person's mind at ease. According to a 2006 Kaiser Family Foundation survey, 40% of people in the U.S. believe that HIV can be transmitted by kissing, sharing a drinking glass, or touching a toilet seat. This is a barrier that can be addressed through prevention education and through pre-test counseling. The downside is the time involved. That time can be a psychological barrier for the patient as well as for the provider who sees several patients a day and may not want to devote the time needed. This can lead to the test not being offered in the first place. Many newer statutes attempt to streamline the pre-test phase of testing. This can often be achieved by using posters, brochures, and videos, cutting back the time needed for one-on-one counseling.

The main psychological barrier is the anxiety. There are two methods of testing, a standard blood draw or rapid oral testing. With the rapid test, results are available within 20 minutes and nearly all patients stay to receive those results. But results for the blood test can take up to two weeks, and studies have shown that nearly 13% of patients do not return to get the results. This means nearly 2.5 million people get tested but never get their results. The time and anxiety around waiting for a standard blood test is clearly a significant psychological barrier to testing. Increased use of the rapid test could lessen much of the psychological barrier.

Providers often cite written consent as a barrier to testing. Despite some concerns regarding confidentiality, particularly among immigrant communities, studies have shown that written consent is not a significant barrier for patients. An overwhelming majority willingly sign any number of forms for health care, and one more is not a barrier in their minds. Administrators, however, have complained that an additional form, particularly the need to provide it in multiple languages, can be a problem. Though this may not be seen as a barrier for patients, it is important to look at all sides of testing to determine where barriers exist.

Finally, there are physical barriers to testing. Sometimes forms for written consent are not readily available, making the test in many jurisdictions not possible. Technological advances could assist in this effort. Additionally, some patients are simply afraid of needles, and without the option of an oral test don't get tested at all.

Conclusion

Advocates continue to be at odds over the best way to increase the number of people tested for HIV. It is clear, however, that efforts to inform people of their HIV status must be made. These efforts need to be mindful of the many factors that keep people from getting tested, including discrimination and lack of access to health care. Any newly proposed HIV policies should take these factors into account and help people make informed decisions regarding HIV testing, treatment, and care. ■

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The Return of "Hit Hard, Hit Early!"

Just when you thought it was safe to wait . . .

by Mark Milano

As a person living with HIV for almost 30 years, I've had a love/hate relationship with the HIV treatment guidelines put out by the Department of Health and Human Services since 1998. I loved the fact that a panel of experts, including clinicians, researchers, and people with HIV, was meeting regularly to debate and discuss HIV treatment, especially the difficult question of when to start HIV meds (since I wasn't taking them). But I hated that these "guidelines," which often were just best guesses, were treated as gospel by many doctors, including mine.

The guidelines came into being after the introduction of triple combination HIV therapy in 1996. With so many drugs to choose from, and so little data on who should take them, people were hungry for some expert guidance. I recall being told by many doctors and researchers, "You were so smart to avoid sequential monotherapy (jumping from one drug to the next), but now you really have to start combination therapy." The idea was to "hit hard, hit early" – fight HIV with a powerful combination of drugs as early as possible in the course of the disease.

This made sense in theory (if you have a life-threatening infection, why not fight it as early as possible?), but the reality of HIV drugs back then was not so simple. Nasty side effects (one friend called full-dose Norvir the worst poison he had ever taken), ridiculous dosing schedules (Crixivan had to be taken every eight hours on an empty stomach), and the risk of resistance if even a few doses were missed. Add to this the fact that the only hard data on the drugs' ability to extend life came from studies of people with CD4 counts below 200, and you can see why people with higher counts and no HIV symptoms had a hard time with this approach.

The guidelines panel seemed to agree – after recommending treatment for anyone with a CD4 count below 500 or a viral load above 20,000, they backtracked in 2001, advising that "many experts would defer therapy" in people above 350 with a viral load below 55,000. In 2004, the viral load threshold was raised – even if it was above 100,000, the guidelines stated: "most clinicians recommend deferring therapy in those above 350, but some…will treat." In 2007, viral load was removed from the equation and the guidelines became clearer: "therapy should be initiated" in anyone with a CD4 count below 350. But for people above 350, there was still doubt: "the optimal time to initiate therapy…is not well defined."

Raising The Bar

Which brings us to last December's big change. When the panel met, they knew that their earlier decision to recommend treatment for anyone below 350 was now supported by the first major clinical study of when to start – the CIPRA HT 001 study, done in Haiti. People with CD4 counts between 300 and 250 either started HIV treatment immediately or waited until they dropped below 200. The study was stopped early because 23 people who delayed treatment died, compared with only six people who started immediately. Since the study was randomized (people were assigned to start or wait by chance) this was the first hard data proving that 350 was no longer a guess – it was a real benchmark of when to start.

Now the question was: should the starting point be raised even higher? Should we go back to recommending treatment to anyone below 500? It was déjà vu all over again, but with some important differences. First, the drugs today are not like the drugs in the mid-90s. Fewer side effects and easier dosing (including a number of once-a-day regimens) have addressed many of the arguments against early treatment (though of course we don't know the long-term side effects of newer drugs). Second, we know more about what HIV actually does to the body, even at higher CD4 counts. As discussed in the cover story of this issue, we're learning much more about HIV inflammation. Turns out HIV not only suppresses the immune system, it also activates it, which can lead to heart, kidney, and liver disease, and cancer. In addition, the SMART study found that people who interrupted their HIV treatment had a higher risk of death, mainly due to non-AIDS-related causes like heart disease and cancer.

Finally, cohort studies like ACCORD found that people who began treatment at higher CD4 counts – even above 500 – lived longer than those who waited. But cohort studies have one major flaw: people choose what to do themselves, rather than being assigned by chance, like the CIPRA study. When people choose when to start, it's hard to tell if the final result is due only to the treatment or to something else. And even though ACCORD saw a benefit to starting earlier, the difference was small – meaning the result could have been due to other factors.

So we need a study that randomly assigns people to start or wait – and that study has just begun. The START trial will enroll 4,000 people who have CD4 counts above 500. Half will start as soon as they drop below 500, and half will wait until they reach 350. This should give us a definitive answer on when to start – but it won't report results until 2016.

The panel clearly thought that was too long to wait, and decided to take on the issue last December. The final vote was divided on the strength of the recommendation: 21 voted to strongly recommend treatment to anyone below 500, while 17 voted for only a moderate recommendation. Usually, the panel requires recommendations to be passed by a 2/3 majority, but in this case the recommendation was published as a split vote: 55% to 45%.

In January, the San Francisco Department of Health recommended that HIV meds should be offered to "all motivated patients, regardless of CD4 count or HIV viral load… unless there is a reason to defer therapy." Clearly, "hit hard, hit early" has returned.

When it came to people above 500, the panel was split down the middle: 19 voted to recommend treatment, in the hope that it would lower the inflammation and non-AIDS conditions apparently caused by HIV, and 19 voted against, due to concerns about long-term side effects, the difficulty of adherence for people with no symptoms, and the risk of resistance. One panel member, James Neaton, felt that giving HIV drugs to people at low risk of disease could outweigh the "modest predicted benefit." He was quoted in the *New York Times* as saying, "That is why we do randomized trials."

But the new guidelines seem to already have had an effect. In January, the San Francisco Department of Health recommended that HIV meds should be offered to "all motivated patients, regardless of CD4 count or HIV viral load…unless there is a reason to defer therapy." Clearly, "hit hard, hit early" has returned.

In April, Project Inform issued a position paper that simply stated, "all HIV-positive people who are ready to begin treatment should start before their CD4 counts fall below 500." There was no discussion of the data, the controversy, or the split vote on the panel. A few weeks later, the paper was revised to read "if their CD4 counts fall below 500." And in May, they put out another, more detailed statement, to "respond to recent blogs and other conversations that expressed concerns about [our] position paper ... These postings exposed the need for a thorough explanation of the logic ... and contributed to important ongoing national discussion that could help increase agreement about how to save lives."

Decisions, Decisions...

Where does this leave people with HIV? Well, if you're below 350, you now have strong evidence that you should start treatment. In CIPRA, the number of people who died was so much higher in the delayed treatment group that it would have been unethical to continue the study. Perhaps we'll also see such a big difference in the START trial, making it end well before 2016. But perhaps not – if there's no difference between the two groups (meaning no benefit to starting above 500), we won't know for six more years.

What to do in the meantime? That's the big question. If you're below 500 and not on HIV meds, one thing you must do is to start learning about them. Ask your doctor how other patients are doing, talk to friends who are on treatment, read info at trusted sites like acria.org, thebody.com and aidsmeds.com. The more you know about the drugs, the more confident you'll feel about your decision. Then, ask your doctor what he or she recommends – more doctors are urging their patients to start early, but everyone agrees that pushing people to start before they're ready will only lead to missed doses and drug resistance. And if you're above 500, consider joining the START study – the sooner it enrolls, the sooner we'll have clear answers on when to start.

Finally, don't start unless you're convinced that it's the right time for you – if you have doubts, express them. Ask your doctor why you should start treatment – after all, it's your body. If you're ready to start, go for it – but take the time to learn about adherence before you start. Many people develop resistance to their first regimen because they didn't understand the consequences of missed doses. Ask to talk with an adherence counselor to put a plan in place to avoid missed doses.

If you're not ready to start even though your doctor recommends treatment, make the effort to learn more about the arguments for and against early treatment. Above all, don't base your decision on what the guy down the street thinks! Talk to real experts and look at real data – don't trust rumors and myths about the "conspiracies" behind HIV drugs. Making an informed decision will lead to the best result for you. ■

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HIV: The New and the Now

by Lisa Frederick

In my eight years at ACRIA, I have given workshops on topics ranging from the immune system to domestic violence. But "What's New in HIV?" is definitely one of my favorites, because I never know exactly what I want to focus on until just before the training.

To me, this topic is always evolving. A few days before, and even up to the day I present, I look for new, cutting-edge, and interesting HIV-related topics, whether clinical or social. I reach out to other ACRIA staff to see if they've come across anything new in their research. I want my participants to walk away with information they didn't have walking in.

I also want them to understand how our knowledge of HIV has changed over the years, so I begin by asking them to tell the group the number of years they have worked in HIV. There's always a wide range in the room – from five days to 15 years – which is great for what I want to get across. The number of years a provider has worked in the field is important. When I began in this field twelve years ago, my clients were often dying. I can remember attending three funerals in one week. Things are so different now, and I want them to feel that.

Clients' needs have also changed. It's important for service providers to realize that the services we provided a decade ago are not the same ones that are needed today – it's a new day.

I begin with an exercise called "Then, Present, Future." The participants are broken into groups, and each group shares what was happening in HIV ten years ago, what's going on now, and what they think HIV will look like ten years from now. It helps if they understand how things have changed over time. One recent participant, for example, brought up the fact that she and her colleagues always discuss sexual practices and risk reduction with their clients, and those in the room who were doing HIV work 15 years ago admitted, "We never went there." Today's providers have that conversation more often and are able to tell the room a thing or two about sexual risk reduction – and usually do! Some participants report that they even take notes.

Clients' needs have also changed. For example, we've come a long way, especially in communities of color, on how we view mental health services. It's important for service providers to realize that the services we provided a decade ago are not the same ones that are needed today – it's a new day.

In every "What's New?," I talk about microbicides (topical products being studied to reduce sexually transmitted infections, including HIV). What I say about them depends on what the latest research shows, but I always include the topic. And every time, the majority of people in the room have never heard of microbicides. I usually ask, "So why do you think it's been so hard finding one that works?" One man in a recent workshop replied, "Well you know how women are – everything just hurts them down there." Before I could respond five women snapped back, "Oh, no, he didn't!" I did damage control and explained that early trials had not found the first candidates to be effective (see article on page 5). We all laughed and moved on. Microbicides are a great topic and everyone leaves with plans to keep their eye out on "what's next" with microbicides.

Another topic that I find of great interest is the ever-changing guidelines on when to start HIV medications. Everyone chimes in on this one, since no matter how long you've been doing this work, when people should start HIV meds is a constant discussion. People share stories about clients who took part in the first trials of AZT and those who are only taking one pill a day now. Still, someone always seems to say, "Yeah, that AZT is a killer." Teaching point! We then look at the history of AZT – how it was used at very high doses back in the '80s, how it is used now, and how successful it has been in preventing HIV transmission during childbirth.

I always include epidemiology so we can see the change in the who, what and where of the epidemic. When I show the change in AIDS cases for African-American women, it always leads into an in-depth conversation on why the face of HIV has changed so drastically over the years. It's an interesting but sometimes disturbing conversation.

During one training, someone told us about a client who said he would never use AZT, ever. When asked what regimen he was on, he responded "Trizivir," which actually contains AZT! The counselor just didn't have the heart to tell him. The guidelines are a great "What's New?" topic because it not only increases participants' understanding of HIV meds, but also shows how even the experts are constantly debating this topic.

In a recent training we talked about HIV vaccine research, which always brings up opposing views. I shared the latest developments in vaccine research, and the room was divided as to the hope of finding a vaccine or cure. One woman spoke eloquently of her hopes and prayers for a vaccine so that her children and grandchildren could be free from the risk of an infection that would change their lives forever.

Vaccines and a cure can be emotional topics, and there are always those who express the belief that they will never be available because "they" (those in power) don't want them to. Conspiracy theories are still alive in some communities.

Vaccines and a cure can be emotional topics, and there are always those who express the belief that they will never be available because "they" (those in power) don't want them to. Conspiracy theories are still alive in some communities, and we discuss this. I never let it consume the training but it is an important topic, since anything that is a force in the community should be addressed. We talk candidly and discuss ways to approach it so that these suspicions don't hinder clients' efforts to stay healthy. I always end the discussion by sharing that we continue to learn from vaccine research – even its failures – and that in order to find a vaccine, we actually need to learn something we don't know yet. I urge them to stay hopeful as research for therapeutic as well as preventive vaccines continues.

I also feel it's important to include social issues in this workshop. We often talk about how HIV stigma has stayed the same in some ways and changed in others. During one training I pointed out that there were a lot of Gay Pride events happening in Harlem that year, and that got a lot of reaction from the room. Some people said, "It's about time!" but others said, "Watch out – it's a trap to get us all in one place!" We all laughed, but then we talked seriously about stigma and cultural competence. This led to a deep conversation about how different social, racial, and ethnic groups view and experience HIV stigma. These are often new conversations for participants and give service providers a different perspective when offering services to their diverse clients.

I always look forward to conducting "What's New in HIV?" because along with the participants I learn new things every time. ■

The Cult of HIV Denialism

by Jeanne Bergman, PhD

More is known about HIV than about any other virus. Less than three decades ago, doctors were perplexed by the appearance of Kaposi's sarcoma and Pneumocystis pneumonia (PCP) in young gay men. Since then, scientists and doctors, spurred by the activism of people with AIDS, discovered the virus now called HIV and proved that it causes AIDS by crippling the immune system until the body can no longer resist life-threatening infections.

Scientists around the world have isolated HIV, photographed it with electron microscopes, and sequenced the genomes of its different subtypes. There are now highly accurate tests for HIV antibodies and the virus itself, and increasingly effective and tolerable antiretroviral drugs (ARVs) for its treatment. Science is a gradual process, and there is still much that is not fully understood about HIV, but the evidence that HIV exists, is transmissible by blood, semen, and vaginal fluids – and that it causes AIDS – is vast and thorough.

The Denialists and Their Cult

And yet there are thousands of people who persistently reject these facts. They believe that HIV is harmless or doesn't exist. Some argue that AIDS has other underlying causes, such as drugs, depression, "dirty" sex, stress, malnutrition, or conventional medicine. Others say that AIDS is just an artificial clustering of familiar diseases. Those who reject HIV/AIDS science call themselves "AIDS dissidents," but others usually refer them to as "HIV denialists" because they elevate personal denial into an ideology.

Most people are astonished by the existence of HIV denialism. "I had no idea there were 'AIDS deniers,' and I still don't understand why someone would believe such a thing," a blogger wrote upon reading of the deaths of denialist Christine Maggiore and her young daughter, both from AIDS. What is most baffling is the persistence of irrational beliefs, held firmly despite the evidence, despite the terrible deaths, and despite the absence of a coherent alternative theory. How can people ignore both scientific evidence and their own failing health? How could Maggiore do nothing to prevent HIV transmission to her children? How could she allow her child and herself to die needlessly? And how could her admirers, initially frightened, go on to rebuild the wall of denial?

HIV denialism can be understood if we view the movement as a kind of cult. Denialists refer to HIV medicine and science as "the orthodoxy," giving the field a religious framework, and imagine themselves in an oppositional, visionary role.

The persistence of the HIV denialism can be understood if we view the movement as a kind of cult. Denialists refer to HIV medicine and science as "the orthodoxy," giving the field a religious framework, and imagine themselves in an oppositional, visionary role. Many of the features that social scientists find typical of cults characterize the denialists. Most fundamentally, they maintain an intense "us-versus-them" worldview. Those inside belong to an exalted and secretive group – they feel superior but persecuted for knowing a hidden truth. They believe that the pharmaceutical industry, governments, researchers, clinicians, the United Nations, AIDS activists, foundations, and HIV organizations are united in an elaborate global plot, which ex-traffic cop Clark Baker calls "the most significant criminal conspiracy I have ever imagined" to kill healthy people with toxic drugs for profit.

Doctrine and Indoctrination

Many HIV denialists adopt alternative health and spiritual beliefs, including consciousness-altering practices that are typical of cults. The use of hypnosis by HEAL-New York stands out. Members believe that simply being told that they are HIV-positive makes people sicken and die. HEAL's leader, Michael Ellner, uses hypnosis to extract people from the deadly mental "AIDS Zone" and to make them feel "at peace with testing positive."

Ellner is not alone in thinking that words kill but viruses don't. Cult scholars call this "mystical manipulation." Denialist Matt Irwin developed the theory in *AIDS and the Voodoo Hex*: "The severe, acute psychological stress of being diagnosed 'HIV Positive' is quickly transformed into a severe, chronic psychological stress of living with a prediction of a horrifying decline that could start at any time. This causes a suppression of the immune system, with selective depletion of CD4 T-cells.… These factors have been studied in healthy people where they create the very same immunosuppression and immune dysregulation that may later be called 'AIDS.'"

Denialist Michael Geiger is another proponent of "dangerous" thoughts, and even accused another dissident of helping to kill Christine Maggiore by worrying about her. "Have we as yet learned nothing … of how easy it is to plant projections of sickness and death onto our own selves, as well as our friends, acquaintances or

even onto our children and thereby help to create those fears into our realities?" Ironically, Celia Farber regularly "projects" in just this way: "I feared for [Maggiore's] life, always. I feared the battle would kill her, as I have felt it could kill me, if I couldn't find enough beauty to offset the malevolence. This is a deeply occult battle, and Christine got caught in its darkest shadows." Farber also blames the "AIDS orthodoxy" for long-distance mental homicide: "This is voodoo, what they are doing to [South Africa's denialist Health Minister] Manto. It is heartbreaking. I sometimes think they killed [Maggiore's daughter] EJ with their voodoo, too. What did EJ die of? Can anybody explain it and does it look like anything anybody has ever seen?" (EJ died of PCP.)

Cults often manipulate feelings of shame and guilt to control their members. Because both AIDS and the activities associated with HIV transmission are stigmatized, the HIV-negative denialist leadership often degrades those who have HIV, even if they are dissidents themselves. Peter Duesberg has always blamed AIDS in gay men on poppers and promiscuity; he dismisses those who say they didn't engage in either behavior as liars. Clark Baker says that AIDS was invented because "a small group of promiscuous, addicted, nitrite-huffing, gonorrheal and syphilitic bath house veterans began to get sick" and "refused to accept blame for their self-destructive behavior." A poster on a denialist forum attributes AIDS to "premature aging" from "snorting poppers, doing meth, drinking heavily, smoking heavily, eating poorly, not sleeping, having unprotected sex and taking the various pathogens of hundreds of sexual partners into your body."

HIV-positive denialists who get sick are blamed for lacking commitment: "Given a choice between the opposing ideas of dying from the deadly HIV product or living a long healthy life based on the dissident belief that the HIV product is nothing more than a baseless commodity being sold by junk merchants, chosing [sic] the dissident dream is the far better choice. A pseudo dissident … will use the dissident view as a survival coping device … When ordinary illness strikes and they run to RX drugs and suffer the very types of health decline that the dissident model predicts, they attack the dissident message."

Denialists who die from AIDS are often posthumously smeared as liars and secret addicts. When Raphael Lombardo died, Peter Duesberg wrote, "In hindsight, I think his letter was almost too good to be true. I am afraid now, he described the man he wanted to be and his Italian family expected him to be, but not the one he really was." (Duesberg meant that Lombardo lied about drug use.) Liam Scheff rolled the reputation of Mark Griffiths down a slippery slope of innuendo into the gutter: "I knew Mark; he was cogent when I worked with him – never anything but. Almost. Sometimes he was – once or twice he'd been – a bit groggy. But he told me that it was alcohol. In fact he told me that he did consume alcohol – perhaps more than he should." Scheff said drinking, not AIDS, killed Griffiths.

Creating Pariahs

Like those leaving a cult, former denialists are treated with extraordinary hostility. Dr. Joseph Sonnabend was one of the first physicians to treat people with AIDS. He insisted on a very high threshold of evidence that HIV causes AIDS, was cautious in prescribing unproven treatments, and recognized that co-factors, such as drug use and frequent STDs, influence an individual's risk of infection upon exposure and how fast HIV disease progresses. Denialists have often claimed Sonnabend as one of their own. When clips of him were used in the denialist film "House of Numbers" to support the denialist perspective, Sonnabend responded with a scathing blog at Poz.com, repudiating the film's message and affirming that HIV causes AIDS and that ARVs save lives. He wrote: "It is hard to adequately convey the feelings of a physician who was able to finally help his patients in the mid-1990s, having lost hundreds to this disease before that time. By the time these drugs became available about 400 of my patients had succumbed to AIDS, a dreadful rate of mortality. The effect of these drugs was life saving to those with advanced disease whose survival had been limited before. The portrayal of these drugs as in effect only toxic is so unfair."

Sonnabend was immediately savaged by denialists for betraying the cult. In one forum, "Ellis" wrote: "[Y]ou're a disgusting fraud, in my opinion, having once bravely stood apart from the racket, now pointing fingers and calling names of those who still have the decency to not be bought and sold for dollars and popularity contests. Who cares if HIV causes AIDS, or ten thousand things cause AIDS?… Are you attempting to denigrate the film because of your own outlandish, humiliating lack of composure on camera? Because you sound like the old boozy floozy you really might be, not so

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deep down? Because you sold out to corporate pseudo-science a long time ago, do you now pour hatred onto those who still aren't satisfied with the one-size-fits-none industrial diagnosis? Shame on you, deep, deep, deep shame. You absurd old sell-out."

Celia Farber similarly attacked Sonnabend on the *Spectator*'s website, accusing him of personal and medical treachery: "I have countless hours of tapes from the ever shifting but consistently indignant Joe Sonnabend dating as far back at 1988 … through 2001, if not longer. After that, he became impossibly sycophantic to the orthodoxy.… As for me, like everybody else under Joe's Bus, I forgave him because he seemed so abashed. I even invited him to my wedding. But he is a weak, dishonest man without any integrity, who loves the sensation of throwing everybody under the bus." Sonnabend's sin was to continue to evaluate the evidence, until the proof that HIV causes AIDS and that HAART is an effective treatment was conclusive.

Controlling the Flock

Within cults, the milieu is controlled and members are isolated. For denialists, who have no ashram, this happens online and in small groups. People worried about HIV are urged not to take the antibody test, to avoid mainstream information about AIDS, and to "stay as far away from allopathic doctors as possible."

Robert Lifton, a scholar of cults, identified the "principle of doctrine over person" as a characteristic feature. This doctrine "is invoked when cult members sense a conflict between what they are experiencing and what dogma says they should experience. The internalized message … is that one must negate that personal experience on behalf of the truth of the dogma. Contradictions become associated with guilt: doubt indicates one's own deficiency or evil." Many HIV-positive denialists struggle with the reality of failing immune systems, which undermines their belief that HIV is irrelevant. The long list of denialists who have died from AIDS (posted on AIDStruth.org) contrasts with the fact that not one of the HIV-negative denialist leaders has died young, let alone with multiple strange infections that happen to be AIDS-defining illnesses.

Some HIV-positive denialists defy the prohibition on HIV treatment when they develop AIDS; they start ARVs and experience a rapid return to health. But instead of abandoning denial, many struggle to frame an alternative explanation for the success of the meds. Noreen Martin insists that her AIDS is not viral: "My own experience with AIDS was due to a lifetime of negative health issues. When extremely sick, I took the medicines, ate healthy, took over 50 supplements a day, and had a good attitude. So, within a few months I was as good as new." She stopped ARVs for three years. "During this time," she wrote, "my fatigue slowly came back, my CD4s dipped and my viral load increased to over 3 million. Nevertheless, I never placed much stock in either of these numbers because after extensive research, I realized that neither were [sic] related to health. It was other conditions that caused the problems and the ARVs were powerful enough to keep them at bay.… Last fall, I became extremely tired again after being anemic for almost a year and fighting lymphedema for months, I took the ARVs, as I could barely get off the couch and could not function in life." Her health again improved.

PETER DUESBERG HAS ALWAYS BLAMED AIDS IN GAY MEN ON POPPERS AND PROMISCUITY; HE DISMISSES THOSE WHO SAY THEY DIDN'T ENGAGE IN EITHER BEHAVIOR AS LIARS.

Another denialist said, "I have seen many friends get better on ARVs, but my understanding has always been that these drugs are broad spectrum in their efficacy – that they serve to kill virtually all pathogens, but also all the 'good stuff' in our bodies." Another, a thoughtful woman struggling to reconcile her recurrent illness with dogma, wrote: "All I can say is that I'm doing what seems to be working at the time. If it stops working, I'll make a new plan. And just because they call them antiretrovirals doesn't mean that's what they are." The only way they can remain alive and in the dissident camp is to pretend that ARVs, so precisely designed to target the ways that HIV infects T-cells, are a supercharged all-purpose germicide.

Deprogramming

Some denialists with HIV are unable to ignore their own experience, and are pushing back against the cult rhetoric. One weary man, positive since 1996, wrote, "Frankly, I'm sick of the questions at this point. Some of us here are experiencing strangely similar symptoms. Some well known people have died just like the orthodoxy said they would. At what point are dissidents going to start asking the important questions, rather than repeat the words 'AIDS ZONE' over and over? I'm not in any AIDS zone, but something is happening beyond my control. I have never been closer to taking Atripla than I am today. I hate to type that ... but it's true."

The denialist movement is also deeply split by conflicting theories of AIDS causality, different schools of quackery, and the basic question of whether the virus exists or not. Their unity is only maintained by their ritual invocation of long-disproved claims and their refusal to engage with scientific evidence. The most successful denialist propaganda avoids making direct claims and persuades only by innuendo and inference, because clear and specific statements generate hostility within the movement and can be easily disproven by evidence.

Still, it is very difficult for believers to break free of HIV denialism. Dissidents build their worldviews, their sense of themselves as heroic and embattled, their careers in journalism and alternative medicine, and their webs of social relationships around their rejection of HIV science and medicine. They have a lot to lose if they acknowledge that they are simply wrong. But as HIV treatments get better and better, and people with HIV live long and healthy lives using them, the psychological impulse to refuse to accept what was once a terrible diagnosis is diminished. Perhaps soon the only AIDS denialists will be HIV-negative people far removed from the communities most affected by the epidemic, and their cult won't matter at all. ■

Jeanne Bergman is a veteran AIDS and human rights activist in New York City.

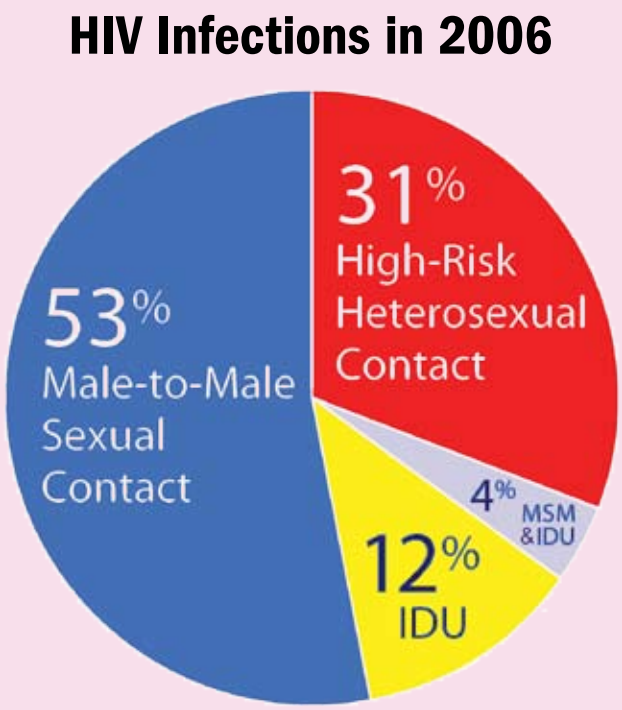
HIV and Gay Men: A Global Concern

The passage of health care reform (the Patient Protection and Affordable Care Act) on March 23, 2010 is a major historic achievement. In the grand discussion of who needs comprehensive health care, however, gay men and other men who have sex with men (MSM) were conspicuously absent. The health of gay men has historically been ignored, even during times of major public health crisis. This was especially true during the onset of the AIDS epidemic. Policies and prevention efforts to date have failed to address the needs of this population with necessary funding and prevention services.

In the early 1980s, gay men's health first caught mainstream attention with the rise of AIDS, albeit with stigma and discrimination. During this time, political leaders dragged their feet as the country was gripped with fear stemming from false beliefs about becoming infected through a sneeze or a hug. The failure of policy makers and public health experts to demystify the virus in the early stages of the AIDS crisis has largely influenced the current state of HIV across the nation, specifically among MSM.

In March 2010, the Centers for Disease Control and Prevention (CDC) released staggering new data on the prevalence of HIV and syphilis among MSM in the U.S. The analysis of a number of national data sets on sexual behavior, which defined MSM as men who have had sex with another man within the last five years, revealed that MSM are at least 44 times more likely than other men to contract HIV, and at least 40 times more likely than women to contract HIV. Further, MSM were at least 46 times more likely than other men, and at least 71 times more likely than women, to contract syphilis.

In 2006, MSM comprised 57% of people newly infected with HIV in the U.S., even though the CDC states that MSM are only about 2% of the adult population. MSM are the only group among which HIV rates are increasing in the U.S. However, most gay men practice safer sex and gay men are twice as likely as heterosexuals to practice safer sex.



The impact of HIV among MSM is even more troubling among gay and bisexual men of color. A staggering 20% of new HIV diagnoses in the U.S. occur among black MSM even though black MSM represent only 0.25% of the adult population. New infections have jumped sharply among black and Latino MSM aged 13 to 29.

On a brighter note, President Obama's proposed fiscal year 2010 budget calls for $28 million to increase the reach of HIV testing by expanding HIV prevention targeted at MSM.

Internationally, HIV among MSM is also of great concern. UNAIDS reports that 5 to 10% of all HIV infections worldwide occur among MSM. Though heterosexual sex accounts for the majority of HIV infections worldwide, in some parts of the world men having sex with men is the primary mode of HIV transmission. In fact, the difference in HIV rates between MSM and the general population in many countries is often extreme – in Mexico the rate of HIV among MSM is 109 times greater than among all adults. But the full scope of the global HIV pandemic is unclear, since most countries lack surveillance systems or prevention efforts for MSM due to high levels of stigma and homophobia.

Because HIV prevention messaging in Africa has been exclusively heterosexual, many MSM believe they are not at risk for HIV. Yet several studies show disproportionately high rates of infection among African MSM. Thankfully, the 2008 reauthorization of the President's Emergency Plan for AIDS Relief (PEPFAR) calls for prevention and research targeting MSM. An end to criminalization, which drives homosexuality underground, is also key to fighting HIV among MSM.

The health of gay and bisexual men and other MSM is a global concern that deserves greater attention, commitment, and allocation of resources. Despite strides in HIV treatment, AIDS continues to take the lives of many people, including MSM. Accurate surveillance systems and innovative preventive measures that target MSM are vital to a comprehensive strategy both domestically and abroad. ■

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Protect LGBT Youth!

A CALL TO ACTION

Senator Al Franken and 22 other U.S. Senators recently introduced the Student Non-Discrimination Act (SNDA) to provide federal protections to students who are, or are perceived to be, lesbian, gay, bisexual or transgender (LGBT) from harassment, bullying, and violence in public schools. It would also prohibit schools from discriminating against LGBT students or ignoring harassing behavior.

Studies show that an unsafe educational atmosphere can push students out of school and into high-risk behavior. Several surveys report that nearly 9 out of 10 LGBT students have been bullied in school, and other studies indicate that LGBT youth are bullied two to three-times more often than their heterosexual peers. Stressful school environments have been shown to increase LGBT students' likelihood to skip school, underperform academically, and drop out. However, in schools with Gay Straight Alliances and other gay-affirming interventions, young gay and bisexual men are less likely to engage in HIV risk behavior than in schools without these interventions.

It is critical to keep our nation's youth safe in schools, including LGBT youth. Call your Senators today and ask them to support SNDA!